

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

13370



2 - LABEL SAMPLE

**000001**

# Food and Drug Administration Office of Regulatory Affairs Collection Report

For Sample Number: 32555

DRAFT

*Servicing Lab not yet specified - ARP*

<b>Flag</b>		<b>Flag Remarks</b>			
Complaint Sample		Sample collected per MedWatch #13370 assignment directive			
<b>Episode Number</b>	<b>Origin</b>	<b>Basis</b>	<b>Sample Type</b>	<b>FIS Smpl Num</b>	<b>Status</b>
	Domestic	Surveillance	Investigational	99920648	In Progress
<b>FEI</b>	<b>Date Collected</b>	<b>Product Code</b>	<b>Responsible Firm</b>	<b>PAC</b>	<b>Hours</b>
1000117125	24-MAR-99	54Y9Y99	Manufacturer	03F800	
<b>Related Smpl Num</b>	<b>Position Class</b>	<b>Sampling District</b>	<b>NDC Number</b>	<b>Permit Number</b>	<b>Storage Rqrmnt.</b>
	INV	DET-DO			Ambient
<b>Dealer is Consumer Crx/DEA Schedule</b>		<b>Recall Num</b>	<b>Consumer Compl. Num</b>	<b>Brand Name</b>	
Yes			DET-0833	Metacuts	

**Product Description**

Beige capsules with grainy substance inside

**Product Label**

See continuation

**Reason for Collection**

Complaint/Injury F/U (DET-0833) which generated MedWatch #13370. CFSAN facimile from HFS-636, dated March 12, 1999

**MFG Codes**

WN2658A

**Expiration Date**

0901

**Firm Legal Name**

Metaform

**Address**

22647 Ventura Blvd. #346 Woodland Hills, CA 91346 US

**Type of Firm**

Shipper

**Firm FEI**

3002654293

**FCE**

Weider Nutrition International

2002 South 5070 West Salt Lake City, UT 84104 US

Manufacturer

1000117125

**Size of Lot**

1 bottle containing 10 capsules

**Est. Value**

\$20

**Rcpt Type**

FDA484

**Date Shipped & Doc. Ref.**

**Description of Sample**

See continuation.

**Method of Collection**

1 glass bottle containing 10 capsules collected from consumer

**How Prepared**

See continuation

**Collector's Identification on Package and/or Label**

"32555 3/24/99 ARP"

**Collector's Identification on Seal**

"32555 4/1/99 Anthony R Petriella"

**Sample Delivered To**

DET-DO Sample Custodian

**Date Delivered**

**Orig C/R & Records To**

DEN-DO

**Lab w/Split Sample**

**Lab**

*awaiting assignment*

**Document Number**

13370

**Document Date**

03/12/1999

**Document Type**

Other

**Document Remarks**

CFSAN facsimile request for follow-up #13370: Attachment A1/A3  
Complaint/Injury follow-up: Attachment B  
Affidavit signed by Mr. [REDACTED]  
Attachment C1,C2  
Photocopy of product label: Attachment D  
Carbon copy of product Receipt for Sample: Attachment E

DET-0833

02/22/1999

Other

03/25/1999

Affidavit

FDA-484

03/24/1999

Other

Other

000002

Date: 04/27/1999

Page: 1 of 3

Complaint/Injury F/U DET-0833  
3/24,25,30/99 ARP Att 7

*not attached  
orig 4 to rem  
in det  
noted lab  
specification*

# Food and Drug Administration Office of Regulatory Affairs

## Collection Report

For Sample Number: 32555

**DRAFT**

FDA-415a

03/24/1999

Other

Original official seal: Attachment F

### Remarks

See continuation.

### Payment Amount

\$0.00

### Payment Method

No Charge

### 704(d) Sample

Yes

### 702(b) Portion

No

### Collector's Name

Anthony R Petriella

### Name of Signer

### Date & Time of Signature

ET

### Meaning

Date: 04/27/1999

Page: 2 of 3

**000093**

Complaint/Injury F/U DET-0833  
3/24,25,30/99 ARP Att 76

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 32555

DRAFT

Continuation:

Product Label

Metaform Metacuts dietary supplements packaged in a brown glass bottle labeled, in part "\*\*\*\*METAFORM\*\*\*PRE-EXERCISE AND ENERGY BOOSTER\*\*\*METACUTS\*\*\*60 CAPSULES\*\*\*WN2658A EXP0901\*\*\*"

Description of Sample

10 beige capsules with grainy material inside. Capsule container is constructed of brown glass with a black screw cap top. Product label is brown, white and gold with white, black, gold and red lettering.

How Prepared

Sample identified as "32555 3/24/99 ARP". Sample placed in brown paper bag identified "32555 3/24/99 ARP" and sealed as "32555 4/1/99 Anthony R. Petriella"

Remarks

Spl was temp sealed on day of collection (3/24/99) and stored in locked cabinet until next day. On 3/25/99 spl then transferred to locked spl room until 4/1/99. On 4/1/99, spl orig. seal broken for purposes of product label descr. Spl was then again immediately off sealed. Spl collected from consumer, Mr [REDACTED]  
Send [REDACTED] results there

Date: 04/27/1999

Page: 3 of 3

000004

Complaint/Injury F/U DET-0833  
3/24,25,30/99 ARP Att 7C  
HJC



# METAFORM

PRE-EXERCISE AND  
ENERGY BOOSTER

DIETARY SUPPLEMENT  
60 CAPSULES

000005

State of the art, preworkout formula  
METAFORM™ Thermogenic Blend  
ascorbates; methylxanthines,  
salicylates. When these compounds are  
used in a diet and exercise program, they  
increase energy expenditure and work output.\*

It has been evaluated by the  
FDA. This product is not  
intended to cure or prevent any disease.

Recommended dosage: Taking more  
than recommended will not be more effective and  
may have adverse effects, including heart attack.  
Do not use if you are pregnant or  
have high blood pressure, glaucoma, stroke,  
heart disease, or any psychiatric disorder,  
are taking drugs for depression, psychiatric or  
heart disease, methyldopa, or any  
other drug containing pseudoephedrine or  
other stimulants found in cough/cold,  
weight loss products), or if you are prone  
to difficulty in urination due to prostate  
enlargement. Consult your health care professional prior to  
use. Discontinue use and contact a  
physician immediately if dizziness, severe headache,  
nausea, rapid and/or irregular  
heartbeats in behavior, or nausea occurs.

For persons under the age of 18.  
DO NOT USE.  
KEEP WITH LID TIGHTLY CLOSED  
ONE SERVING A DAY



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52472 3

**Directions: Take four (4) capsules 30 to 60 minutes prior to workout.**

## Supplement Facts

**Serving Size: Four (4) Capsules**

**Servings Per Container: 15**

Amount Per Serving	% Daily Value
Chromium (as picolinate)	200 mcg 170%
Magnesium (as oxide)	100 mg 25%
Potassium (as citrate)	100 mg 4%
Guarana ( <i>Paulinia cupana</i> ) (150 mg caffeine from 15% standardized extract) (seed)	1000 mg *
Citramax™ (min. ~50% (-)-HCA)	1000 mg *
Garcinia cambogia (fruit)	
Ma Huang ( <i>Ephedra sinica</i> ) (16.5 mg ephedrine from standardized extract) (whole herb)	275 mg *
L-Carnitine tartrate	100 mg *
Quercetin	100 mg *

\* Daily value not established

\*Daily Value not established

**Other Ingredients:** Magnesium silicate and magnesium stearate.

**DISTRIBUTED BY:**  
**METAFORM®**

22647 Ventura Blvd. #346  
Woodland Hills, CA, USA 91346  
1-800-439-8048  
[www.realmuscle.com/metaform](http://www.realmuscle.com/metaform)

**DIABETIC/HYPOGLYCEMICS:** Use only under a physician's supervision.

Citrimax™ is a trademark of InterHealth Corp.

**METACUTS™** is an oil-free skin and energy enhancer.\* **METACUTS** contains several ephedrine isomers, bioflavonoids, and other alkaloids combined, with a sensible diet to encourage a rise in daily energy.

\*These statements have not been evaluated by the Food and Drug Administration. Intended to diagnose, treat, or

**WARNING:** Do not exceed doses than the recommended dosage. May increase the risk of side effects, stroke, seizure, and death. Do not nursing or if you have high blood diabetes, heart or thyroid disease, or if you are taking certain drug emotional conditions. Paroxetine product containing epinephrine, phenylpropanolamine (or other allergy, asthma and was used to seizures, or if you have prostate enlargement. Consult your doctor use if you are using MAO inhibitors, weeks or any other medication, health professional immediately, shortness of breath, chest pain, or heartbeat, noticeable changes in Not for long-term use.

Not intended for use by persons  
KEEP OUT OF REACH OF CHILDREN  
STORE IN A COOL DRY PLACE, W  
DO NOT USE MORE THAN ONE SE

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WN2658A  
EXP0901

APR 24

32555 3/24/99

Acms 13370  
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MAX-OUT is an all new state of the art, preworkout formula  
energy enhancer. MAX-OUT's Thermogenic Blend  
contains several ephedrine and methylxanthines,  
caffeine, and other compounds. When these compounds are  
combined with a sensible diet and exercise program, they  
can help increase daily energy expenditure and work output.\*

MAX-OUT has not been evaluated by the  
Federal Drug Administration. This product is not  
intended to diagnose, treat, cure or prevent any disease.

Do not exceed recommended dosage. Taking more  
than recommended dosage will not be more effective and  
is at risk of side effects, including heart attack,  
stroke, and death. Do not use if you are pregnant or  
nursing. If you have high blood pressure, glaucoma, stroke,  
heart, liver or thyroid disease, or any psychiatric disorder,  
or are taking certain drugs for depression, psychiatric or  
other conditions, Parkinson's disease, methylxanthines, or any  
other containing ephedrine, pseudoephedrine or  
methylxanthines (sympathomimetics found in cough/cold,  
dietary and weight loss products), or if you are prone  
to seizures, or if you have difficulty in urination due to prostate  
enlargement. Consult your health care professional prior to  
use if you are using MAO inhibitors now or within the last two  
weeks of any other medication. Discontinue use and contact a  
health professional immediately if dizziness, severe headache,  
palpitations of heart, chest pain, rapid and/or irregular  
heart rate, noticeable changes in behavior, or nausea occurs.  
Keep away from children.

Intended for use by persons under the age of 18.

KEEP OUT OF REACH OF CHILDREN.

STORE IN A COOL, DRY PLACE, WITH LID TIGHTLY CLOSED.

DO NOT USE MORE THAN ONE SERVING A DAY.



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WN2658A  
EXP0901

METACUTS™ is an oral  
and energy enhancer. It  
contains several essential  
vitamins, minerals, and other  
combined, with a number of  
encourage a rise in daily energy.

These statements have not  
been evaluated by the  
Food and Drug Administration.  
Intended to diagnose, treat,

**WARNING:** Do not exceed  
the recommended dose.  
They increase the risk of  
stroke, seizure, and death.  
Nursing or if you have high  
blood pressure, heart or kidney  
disease, or if you are taking  
medication. Do not use  
product containing other  
phenylpropanolamine (PPA)  
allergy, asthma, and use  
to increase, or if you have  
overweight. Consult your  
doctor if you are using METACUTS  
for more than 10 weeks or any other  
health professional has  
shortness of breath, chest  
pain, heartburn, nervousness, dizziness,  
or any other symptoms.  
Not for long-term use.  
Not intended for use by children.  
KEEP OUT OF REACH OF CHILDREN.  
STORE IN A COOL DRY PLACE.  
DO NOT USE AFTER EXPIRATION DATE.

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# METAFORM

PRE-EXERCISE AND  
ENERGY BOOSTER

ACQ  
DIETARY SUPPLEMENT  
60 CAPSULES

000009



# META

PRE-15  
ENERG

000010



Use 30 to 60 minutes

# ent Facts

	% Daily Value
200 mg	170%
100 mg	26%
100 mg	4%
1000 mg	
1000 mg	
276 mg	
100 mg	
100 mg	

and magnesium stearate.

7346  
91346

reform  
sickon's supervision  
Health Corp.

WN2658A  
EXP0901

APP  
APP

32555 3/24/99

METACUTS™ is an all new, state of the art, preworkout formula and energy enhancer. METACUTS™ Thermogenic Blend contains several ephedrine isomers, methylxanthines, bioflavonoids, and other alkaloids. When these compounds are combined, with a sensible diet and exercise program, they encourage a rise in daily energy expenditure and work output.

**These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

**WARNINGS:** Do not exceed recommended dosage. Taking more than the recommended dosage will not be more effective and may increase the risk of side effects, including heart attack, stroke, seizure, and death. Do not use if you are pregnant or nursing or if you have high blood pressure, glaucoma, asthma, diabetes, heart or thyroid disease, or any psychiatric disorder, or if you are taking certain drugs for depression, psychiatric or emotional conditions, Parkinson's disease, methylxanthine or phenylpropanolamine (found in cough/cold, decongestants, allergy, asthma and weight loss products), or if you are prone to seizures, or if you have difficulty in urination due to prostate enlargement. Consult your health care professional prior to use if you are using MAO inhibitors now or within the last two weeks or any other medication. Discontinue use and contact a health professional immediately if dizziness, severe headache, heartbeats, chest pain, rapid and/or irregular heartbeat, noticeable changes in behavior, or nervousness occur. Not for long-term use.

Keep out of reach of children under the age of 18.  
Store in a cool, dry place, with lid tightly closed.  
Do not use more than one serving a day.



# METAF

EXERCISE  
ENERGY BOOST

60 CAPSULES



(4) ~~\_\_\_\_\_~~  
\_\_\_\_\_

	% Daily Average	
200 avg	79%	
100 avg	29%	
60 avg	8%	
1000 avg	"	
(Production average based)		
200 avg	"	
100 avg	"	
60 avg	"	
1000 avg	"	

**WALTER DICKS and TRANSLATION GROUP**

RESULTS BY:  
 TANCORP  
 10000 Blvd. #346  
 Mt. La. USA 71246  
 504-885-8148  
[tnc.com/menform](http://tnc.com/menform)  
 only under a physician's supervision.  
 members of Interscience Corp.

WN2658A  
EXP0901

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[illegible]

9650252472

# METAFORMA

## PRE-EXERCISE AND ENERGY BOOSTER

## RESULTS AND DISCUSSION

# THE

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**Supplement Facts**

Serving Size: Four (4) Capsules  
Amount Per Serving: 100% Daily Value

Proprietary Blend	100 mg	100%
Proprietary Blend	100 mg	100%
Proprietary Blend	100 mg	100%
Proprietary Blend	100 mg	100%
Proprietary Blend	100 mg	100%
Proprietary Blend	100 mg	100%
Proprietary Blend	100 mg	100%
Proprietary Blend	100 mg	100%
Proprietary Blend	100 mg	100%
Proprietary Blend	100 mg	100%

LN2658A  
EXP0901  
10604X3

3255 3/24/99  
APP

**METAFAT** is an all natural blend of the most powerful fat-burning and energy enhancing ingredients. METAFAT is a thermogenic blend of natural ingredients that work together to increase metabolism, burn fat, and increase energy. METAFAT is a thermogenic blend of natural ingredients that work together to increase metabolism, burn fat, and increase energy. METAFAT is a thermogenic blend of natural ingredients that work together to increase metabolism, burn fat, and increase energy.



**METAFAT**

PREMIER  
ENERGY

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